NOV 17 2009

5. 510(k) Summary or 510(k) Statement

510(k) Summary for
Chromsystems MassCheck Immunosuppresants Whole Blood Controls

According to the requirements of 21CFR 807.92, the following information provides sufficient detail to understand the basis for determination of substantial equivalence.

Submitter Name, Address, and Contact Information:

Chromsystems Instruments and Chemicals GmbH,
Heimburgstrasse 3, D- 82143 Munich, Germany
Dr. Andreas Groemping, Regulatory Affairs Manager
Phone: +49/89 18 930-200; Fax: +49/89 18 930-299

Device Name and Classification:

Proprietary Names:

MassCheck Immunosuppressants Whole Blood Controls (Level I-IV, Blank)

Classification name:

Drug specific control materials; Class I DIF (91 Toxicology) 21 CFR 862.3280

Common/Usual names:

Immunosuppressants Control Material

Predicate Devices:

Bio-Rad Laboratories Lyphochek Whole Blood Immunosuppressant Control (K072721)

Waters MassTrak™ Immunosuppressants Kit (K063868)

Device Description:

The Chromsystems MassCheck Immunosuppressant Controls are lyophilized, multi-analyte human whole blood based products containing the analytes Ciclosporin A, Rapamycin (Sirolimus) and Tacrolimus. The Controls are available as four levels + blank.

Prior to use the different lyophilized controls need to be reconstituted by adding the corresponding amount of water as indicated on the respective packing leaflet.

Each donor was tested and found negative for Human immunodeficiency virus (HIV) 1 and 2, Hepatitis B virus (HBV), Hepatitis C virus (HCV) in European blood banks. The tests used were cleared for in vitro diagnostic use in the EU (in compliance with the European Directive 98/79/EC on in vitro Diagnostic Medical Devices as Annex II, List A products) and are also approved by the Paul-Ehrlich-Institute in Germany.

Intended Use:

MassCheck Immunosuppresants Whole Blood Controls (Level I-IV and Blank)

> The Chromsystems MassCheck Immunosuppressant Whole Blood Controls are in vitro diagnostic devices intended to verify performance of various laboratory assay systems that measure cyclosporine, tacrolimus, or sirolimus.

Substantial Equivalence Information:

The predicate and proposed devices are similar in the following ways:

- **Same intended use - in vitro diagnostic devices intended for the calibration and control of laboratory assay systems used in the determination of immunosuppressant specific drug analytes in patient whole blood.**
- **Same analytes**
- **Consist of similar matrices (human whole blood)**
- **Predicates and proposed devices are supplied lyophilized and must be reconstituted**

These devices differ in the following ways:

- **The numbers of concentration levels are different.**

The Chromsystems MassCheck Immunosuppressants Controls are substantially equivalent to predicate devices which are currently legally marketed via the 510(k) process intended for similar use, as demonstrated by the information provided in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Chromsystems Instruments and Chemicals GMBH
C/O Cathy Cambria
Arkin Consulting Group
1733 Canton Lane Suite 103
Marietta, Georgia 30062-2679

NOV 17 2009

Re: k080459
Trade Name: MassCheck Immunosuppressant Whole Blood Controls (Level I-IV plus Blank)
Regulation Number: 21 CFR §862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: Class I
Product Codes: LAS
Dated: November 2, 2009
Received: November 6, 2009

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

Indication for Use

510(k) Number (if known): K080459

Device Name: MassCheck Immunosuppresants Whole Blood Controls (Level I-IV plus Blank)

Intended Use:

The Chromsystems MassCheck Immunosuppressant Whole Blood Controls are in vitro diagnostic devices intended to verify performance of various laboratory assay systems that measure cyclosporine, tacrolimus, or sirolimus.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080459